

Please **answer these questions** if you are registering for the

Train-the-Trainer Workshop

Name _____

Why do you want to become an instructor in Medical Device HACCP?

What are your qualifications?

Describe your willingness and availability to teach in your geographical area.



<http://www.conted.vt.edu/haccp.htm>

COTA CENTER FOR
ORGANIZATIONAL
TECHNOLOGICAL
ADVANCEMENT

Announcing
2 training workshops
for the Medical
Device Industry
and Regulators



Medical Devices HACCP Workshop
February 21-22, 2000



Train-the-Trainer HACCP Workshop
February 23-25, 2000



The Hotel Roanoke &
Conference Center:
A Doubletree Hotel
Roanoke, Virginia

Co-sponsored by
United States Food and Drug Administration
Center for Devices and Radiological Health

In cooperation with Virginia Tech
College of Agriculture and Life Sciences
Department of Food Science and Technology



VIRGINIA POLYTECHNIC INSTITUTE
AND STATE UNIVERSITY

Virginia Cooperative Extension

Center for Organizational and
Technological Advancement

Division of Continuing Education

MEDICAL DEVICES HACCP WORKSHOP (Feb 21-22, 2000)

Who Should Attend?

Professionals and regulators in the medical device industry

CQA's and CQM's who want to prepare for the proposed ASQ HACCP Auditor Exam

Why Should You Attend?

HACCP principles have proven very successful in the food inspection programs of the U.S. Department of Agriculture and the Food and Drug Administration. The Center for Devices and Radiological Health (CDRH) is now promoting HACCP as a management tool to improve the efficiency and effectiveness of medical device inspections as well as the safety of the medical devices.

In This Workshop You Will:

- (1) Understand the relationship between HACCP and the Quality Systems Regulation for medical devices.
- (2) Learn the HACCP fundamentals of risk management to identify critical control points, take corrective and preventive action, and greatly reduce inspection times.
- (3) Learn how to conduct a hazard analysis, develop a HACCP plan for your devices and reduce inspection time to less than three days. You will participate in a small group exercise to conduct a hazard analysis and develop a HACCP plan for a specific product.

The workshop begins at 8:00 am on Monday, February 21, 2000, and runs to 5:00 pm, and continues on Tuesday from 8:00 am to 5:00 pm. You MUST be present for the entire workshop in order to receive an official certificate of training.

How Much Does It Cost?

The registration fee is \$300 and includes the instructional materials, refreshments and lunch on both days. Enrollment is limited to 40 students, so please register early.



Registration

2 training workshops
for the Medical
Device Industry
and Regulators

<http://www.conted.vt.edu/haccp.htm>

Medical Devices HACCP Workshop
February 21-22, 2000



Train-the-Trainer HACCP Workshop
February 23-25, 2000

Please print or type - complete a separate form for each participant.

Name _____
Social Security Number _____
Position/Title _____
Employer _____
*Employer's FID# _____
Address _____
City _____
State _____ Zip _____
Office Phone _____
Fax _____ E-mail _____
Signature _____

Please indicate which workshop(s) you are registering for:

☐ Medical Device HACCP Workshop (Feb 21-22, 2000) @ \$300 per person
☐ Train-the-Trainer HACCP Workshop (Feb 23-25, 2000) @ \$325 per person
(Please complete back of this form) \$_____ total enclosed

Method of Payment: Registration will be processed when payment is received.

☐ Check enclosed. Make check payable to Treasurer, Virginia Tech CE
☐ Credit card: ☐ MasterCard ☐ VISA ☐ AmEx
Cardholder Name _____
Card No. _____ Exp. Date _____

Return by **February 7, 2000** (no staples, tape, or paper clips, please) to:
Conference Registrar, Division of Continuing Education
810 University City Blvd., Suite D
Virginia Tech, Mail Code 0272
Blacksburg, VA 24061
phone (540) 231-5182, fax (540) 231-3306

If you are registering for Train-the-Trainer workshop,
please answer the questions on back.

Office Use	Received	AMT: _____
		CHK#: _____
		DPST: _____
		DATE: _____

*Necessary to process a refund payable to any company, agency or government

How to Register

To register for either or both of these workshops, do one of the following:

- 1) Fill out and mail the Registration Form to the Conference Registrar with your check or credit card information (payment is required before your registration can be confirmed).
- 2) Register by telephone. Call (540) 231-5183 and have your credit card handy.
- 3) Register on the Web at <http://www.conted.vt.edu/haccp.htm>
You must include your credit card information (this is a secure server).

Your registration and payment must be received by February 7, 2000.

Refund Policy: Requests for refunds are honored if received four full working days prior to the beginning date of the course. However, substitutions are accepted at any time.

Location

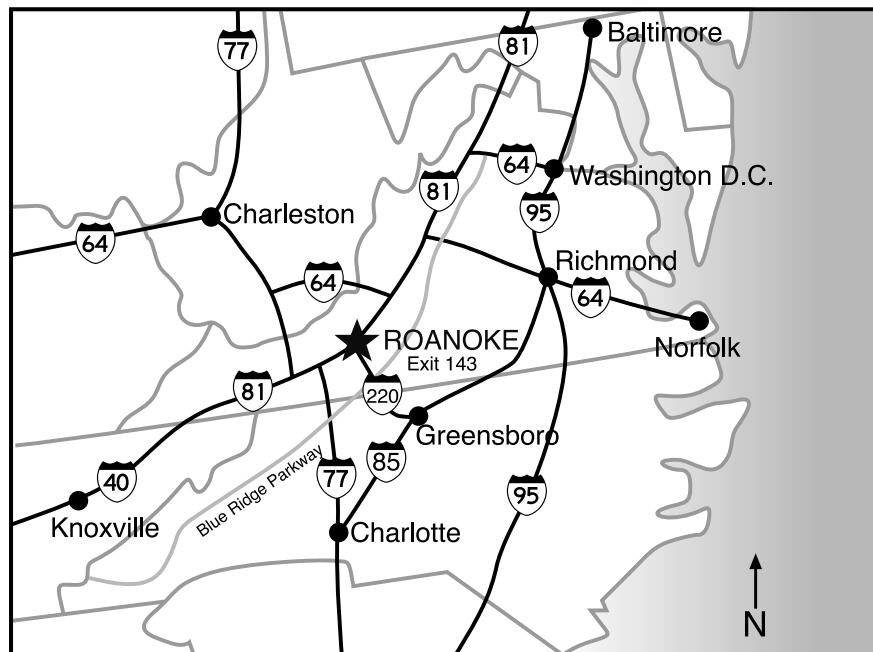
Location of both workshops:

The Historic Hotel Roanoke and Conference Center
Roanoke, Virginia—The Star City of the South

Nestled in the heart of the Blue Ridge Mountains, Roanoke, Virginia is known as the Star City of the South. The Roanoke Star, located on top of Mill Mountain, lights up the evening sky and is a welcome sight for all visiting. Roanoke has it all, from heritage and history to technology and culture. There are international and southern restaurants, Mill Mountain Zoo, Colorado Rockies minor league baseball, semi-professional hockey, museums, golf, tennis, and shopping. Beyond the Star City's glow, there is the Blue Ridge Parkway with breathtaking overlooks, trails, Virginia wineries, Civil War history, and Smith Mountain Lake. Washington, DC, and Williamsburg are only a few hours away. The conference facilities at The Hotel Roanoke and Conference Center (a Doubletree Hotel) are four star, and the hotel boasts of having one of the largest ballrooms on the East Coast. Register early and make your room reservations now.

For additional information on The Hotel Roanoke and Conference Center and/or to make your room reservations online check out the web site at <http://www.hotelroanoke.com/>

For additional information on Roanoke and Tourism, check out the web site at <http://www.visitroanokeva.com/>



Travel and Lodging

The Hotel Roanoke and Conference Center is conveniently located at 110 Shenandoah Avenue within walking distance of shopping and dining in the downtown market district. A covered walkway connects the hotel with downtown.

A block of lodging rooms is being held at The Hotel Roanoke and Conference Center. You may make reservations at the special conference rate by calling (540) 985-5900 or on-line (for Medical Devices at: www.hotelroanoke.com/res/res_hamd.html and for Train-the-Trainer at: www.hotelroanoke.com/res/res_hatt.html). Reservations for the special rate are on a first come first, serve basis, once the room block and/or the hotel is full the conference rate will most likely not be available. Therefore, please make your reservations early and definitely no later than January 21, 2000. You must mention the HACCP Workshop when making your reservation to get the special rate of \$93 single or double occupancy (plus 9.5% taxes).

For additional lodging options check out Roanoke's web site at <http://www.visitroanokeva.com/>

For exact driving directions go on-line

Map your trip on Mapquest: <http://www.mapquest.com>

Travel by Air

The Roanoke Valley Regional Airport (ROA) is only minutes from The Hotel Roanoke and Conference Center. Complimentary shuttle service takes you directly from/to the airport and The Hotel Roanoke and Conference Center. A complimentary phone with a direct line to the hotel can be found in the airport's baggage claim area.

The airport supports these airlines:

USAirways <http://www.usairways.com>

Delta Connection <http://www.delta-air.com>

Northwest Airlin <http://www.nwa.com>

United Express <http://www.ual.com/home/default.asp>

The Greensboro International Airport is only two hours south of Roanoke and has many other flight options at reduced rates.

For More Information

For more specific information on course content, agenda, and list of speakers, please contact Dr. George Flick at (540) 231-6965 (phone); flickg@vt.edu (e-mail).

For other information related to travel, registration, etc., please contact Mike Schroder at (540) 231-5433 (phone); (540) 231-9886 (fax); schroder@vt.edu (e-mail).

Link to related websites:

<http://www.fda.gov/cdrh/qmp/haccp.html>

<http://www.foodsafety.org/afdo>



Virginia Cooperative Extension programs, activities and employment opportunities are available to all people regardless of race, color, religion, sex, age, national origin, handicap or political affiliation. An Equal -Opportunity/Affirmative Action Employer.

If you are a person with a disability and require any auxiliary aids, services or other accommodations for this workshop, please discuss your accommodation needs with Emmett Wright at (540) 231-7084 by two weeks prior to the workshop.

TRAIN-THE-TRAINER HACCP WORKSHOP (Feb 23-25, 2000)

Who Should Attend?

Anyone interested in teaching others about medical device HACCP, including those working in the medical device industry, consultants, educators, and FDA inspectors.

Why Should You Attend?

Building on the fundamentals of the previous workshop, this workshop offers advanced training for those persons who are or will be training others in medical device HACCP. By becoming a dedicated HACCP instructor in your geographical region, you will help us provide training to more individuals in the industry and government, and you will be helping us to reduce the travel time and costs of future training.

What Prerequisites Must Be Met Before You Can Attend This Workshop?

- (1) Completion of the 2-day Medical Device HACCP Training Course.
- (2) Familiarity with the Quality System Regulation 21CFR Part 820.
- (3) Prior experience in risk management and risk analysis, including topics such as FTA and FMECA.
- (4) Familiarity with medical device related ISO standards, such as 9001, 13485, 14971-1, etc.
- (5) Experience in medical device manufacturing, quality assurance, regulatory affairs and auditing.
- (6) Prior teaching experience is recommended.
- (7) A serious commitment to becoming an instructor.

The workshop begins at 8:00 am on Wednesday, February 23, 2000. It will run from 8:00 am to 5:00 pm on both Wednesday and Thursday and from 8 am to noon on Friday. You **MUST** be present for the entire workshop in order to receive an official certificate.

How Much Does It Cost?

The registration fee for the Train-the-Trainer HACCP Workshop is \$325. The fee includes your training manual and materials, your certification, refreshments and lunch on Wednesday and Thursday, and refreshments on Friday. Enrollment is limited to 40 participants, so please register early.

